12 Investigator Responsibilities

PIs are ultimately responsible for the conduct of research. PIs may delegate research responsibility. However, investigators must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility.

The following procedures describe the investigator responsibilities in the conduct of research involving human participants.

12.1 Investigators

12.1.1 Principal Investigators

At CMU only a faculty member may serve as the Principal Investigator (PI) or as the sponsor on a research project involving human subjects. Other individuals, such as research scientists or post-doctoral fellows may be allowed to be the PI at the discretion of the VPR/DGS. The IRB recognizes one PI for each study.

12.1.2 Student Investigators

Students may not serve as PI. They must have a faculty sponsor who fulfills the PI eligibility criteria and who will serve as PI and faculty advisor on the study.

12.1.3 Research Team

These include the PI and other individuals, also known as key personnel, who contribute to the scientific development or execution of a project in a substantive, measurable way, regardless of whether they receive salaries or compensation under the protocol. The research team also consists of individuals who intervene or interact directly with human subjects (including the recruitment or consenting thereof), or who analyze data and/or tissue samples derived from humans.

12.2 Responsibilities

To satisfy the requirements of this policy, investigators who conduct research involving human subjects must

1. develop and conduct research that is in accordance with the ethical principles in the *Belmont Report*;
2. develop a research plan that is scientifically sound and minimizes risk to the subjects;
3. have sufficient resources necessary to protect human subjects, including
    a. access to a population that would allow recruitment of the required number of subjects.
    b. sufficient time to conduct and complete the research.
    c. adequate number of qualified staff.
    d. adequate facilities.
    e. a process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.

f. availability of medical or psychological resources that subjects might require as a consequence of the research.

4. assure that all procedures in a study are performed with the appropriate level of supervision and only by individuals who are licensed or otherwise qualified to perform such under the laws of Michigan and the policies of CMU;
5. assure that all personnel are educated in the regulatory requirements regarding the conduct of research and the ethical principles upon which they are based;
6. protect the rights and welfare of prospective subjects;
7. ensure that risks to subjects are minimized: (i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk; and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;
8. recruit subjects in a fair and equitable manner;
9. obtain and document informed consent as required by the IRB and ensuring that no human subjects are involved in the research prior to obtaining their consent;
10. monitor the data collected for the safety of research subjects;
11. protect the privacy of subjects and maintain the confidentiality of data;
12. when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, include additional safeguards in the study to protect the rights and welfare of these subjects;
13. have a procedure to receive complaints or requests for additional information from subjects and respond appropriately;
14. ensure that pertinent laws, regulations, and institution procedures and guidelines are observed by investigators and research staff;
15. ensure that all non-exempt research involving human subjects receives IRB review and approval in writing before commencement of the research;
16. comply with all IRB decisions, conditions, and requirements;
17. ensure that protocols are submitted for timely continuing IRB review and approval, when required;
18. report unanticipated problems involving risk to subjects or other and any other reportable events to the IRB (see Section 8);
19. obtain documentation of IRB review and approval before changes are made to approved protocols or consent forms; and
20. seek IRB assistance when in doubt about whether proposed research requires IRB review.

12.3 Training and Ongoing Education of Investigators and Research Team

As stated above, one component of a comprehensive HRPP is an education program for all individuals involved with research subjects. CMU is committed to providing training and an on-going educational process for investigators and members of their research team related to ethical concerns and regulatory and institutional requirements for the protection of human subjects.

12.3.1 Initial Education

All personnel must complete the CMU Required Core Modules in the CITI Course in the Protection of Human Research Subjects.

New research protocols and applications for continuing review will not be accepted from PIs who have not completed the initial education requirement.

While research protocols and applications for continuing review will be accepted and reviewed if the PI holds a current certification of training, final approval will not be granted until all co-investigators and members of the research team have completed the initial education requirement.

12.3.2 Waiver of Initial Education

If investigators or members of their research team can verify that they have successfully completed human subjects research training equivalent to that required by CMU, they may request a waiver of the requirement for Initial Education. However, all investigators or members of their research team must complete the requirements of Continuing Education.

12.3.3 Continuing Education and Recertification

All investigators and members of their research teams must meet CMU continuing education requirement every three (3) years after certification of Initial Education through the review of appropriate refresher modules at the CITI web-based training site for as long as they are involved in human subject research. There is no exception to this requirement. Other training may be acceptable. In these cases the researcher should check with the IRB Office for a determination.

Investigators must submit evidence of continuing education prior to the expiration of their training certification. New research protocols and applications for continuing review will not be accepted from PIs who have not submitted satisfactory evidence of continuing education.

Investigators who are also IRB Chair, IRB members, or IRB Office staff will satisfy the training requirements for IRB members and staff described in this policy under Section 2.13.

12.4 Investigator Concerns

Investigators who have concerns or suggestions regarding CMU's HRPP should convey them to the IO or other parties (e.g., college dean, departmental chair) regarding the issue, when appropriate. The IO will research the issue, and when deemed necessary, convene the parties involved to form a response for the investigator or make necessary procedural or policy modifications, as warranted. In addition, the IRB Chair or the DRC will be available to address investigators' questions, concerns, and suggestions.